STATE MEDICAID DUR BOARD MEETING
THURSDAY, July 13, 2006
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:
Charles Arena, M.D.
Lowry Bushnell, M.D.
Dominic DeRose, R.Ph.
Colin VanOrman, M.D.
Brad Hare, M.D.
Wilhlem T. Lehmann, M.D.
Karen Gunning, Pharm D.

Board Members Excused:
Joseph K. Miner, M.D.
Jeff Jones, R.Ph.
Bradley Pace, PA-C

Dept. of Health/Div. of Health Care Financing Staff Present:
Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Richard Sorenson, R.N.
Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.

Other Individuals Present:
Craig Boody, Lilly
Pierre Thoumsin, Amgen
David Case, Astellas
Barbara Boner, Novartis
Tanya Taylor, UCB
Larry Groben, UCB
Sally Lamb, UCB
Lori Howarth, Berlex

Meeting conducted by: Lowry Bushnell

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1. Minutes for June 8, 2006 were reviewed, corrected and approved.

2. Housekeeping:

3. Business Carried Forward:

4. Keppra – Epilepsy Association of Utah Representative was unable to attend meeting and a letter was sent instead. The letter stated "on the behalf of Epilepsy Association of Utah, we endorse the decision to make Keppra available to all patients. Keppra is chemically unrelated to existing medications." Reasoning behind Keppra being brought to the Board is due to a change in indication for the drug. Currently there is a prior authorization

requirement for Keppra, ages 4-16 years, with demonstrated failure on four other anti-epileptic drugs. The indication has was lowered to 4 years. The need for continuing the prior authorization is the issue for discussion. Dr VanOrman suggested that Keppra be available for all patients regardless of age. Pediatric indications for Keppra are very similar to the indications of other second generation AED. There are no safety concerns about the medication. Dr VanOrman favors Keppra being handled in the same manner as all other second generation AED, i.e., without restrictions. Motion to drop the prior authorization entirely, regardless of the age of the patient, was accepted and passed.

5. Growth hormone in Prader Willi Syndrome - Dr. David Donaldson, Clinical Professor, Pediatric Endocrinology, addressed the Board. Growth hormone is indicated for long term treatment of growth failure in children due to an inadequate secretion of endogenous Growth Hormone, growth failure in Prader Willi Syndrome (PWS) and Turner Syndrome, and infants born small for gestational age. Most prescriptions for GH therapy for PWS patients are not for growth failure but rather for the metabolic affects that GH provides. Dr Donaldson stated that most PWS patients do have clinical features of growth hormone deficiency. GH medications are intended to help the patient increase lean body mass and reduce body fat. GH improves the linear growth of PWS patients. Concerns were brought up regarding the contraindications for these medications. They are contraindicated for patients with PWS who are severely obese or have severe respiratory impairment, or sleep apnea. There have been reports of fatalities after initiating therapy with growth hormone in these patients. IGF-1 & IGF-bp3 levels are usually low for patients that have PWS. These levels increase with GH therapy and in addition help with the patient's phenotype and body composition. It was brought into discussion that Medicaid does not cover medications for lifestyle effects. It is difficult to do growth hormone testing on young infants/children, they need to be 3-4 years old to perform stim testing. It requires physicians to rely upon the results of IGF-1 & IGFpb3 levels. Most PSW patients are diagnosed at birth, due to hypotonia. It was mentioned, by RaeDell, that the medication may be available through the manufacturers, especially if they are financing studies for this indication with PWS, if Medicaid will not cover the medication. GH therapy is required through adulthood, due to the fact that if these patients are deficient they will continue to be deficient. Dr. Donaldson acknowledged the contraindications of GH drugs and he expressed that prior to starting GH therapy, the patients must see a sleep specialist for a sleep study to be performed. If patient has not had a sleep study, they will not consider GH drug therapy. A proposal should be created and brought to the Board at the next meeting for the criteria. It was proposed to have a box on the prior authorization for the criteria for growth failure with Prader Willi Syndrome, stating that patients with specific IGF-1 and IGF-pb3 levels and that they have had the appropriate sleep study. Dr. Donaldson could provide the Board with the range criteria of these specific levels of when PWS should receive the GH. Need to pull the studies done on the PWS and determine what was considered to be growth failure. It was decided to re-work the criteria and bring to a future meeting.

6. Dr. Charles Arena, discussing the use of Elidel and Protopic. Dr. Arena recused himself from any vote on the issue due to conflict of interest. FDA placed a black box warning on these medications. They are not indicated for children <2 years of age. In April the Board placed a PA requirement for use of these medications in patients <2 years of age. Dr. Arena,

mentioned that when the disease is treated with topical steroids, patients have the possibility of developing steroid resistance. Systemic effects can also occur due to use of topical steroids. Dr. Arena mentioned that if you wanted to stay within labeled uses, then hydrocortisone 2% cream should not be used either. Dr. Arena brought up that the black box warning, does not say these medications cause cancer, rather: "Although a casual relationship has not been established, rare cases of malignancy have been reported". Actual cancer rate of 0.5% in the general public, would expect up to 3 million malignancies to be reported. Even at normal cancer rate, it would be expected to have 3,000 patients out of the 6 million patients that have used Elidel, to develop cancer. Dr. Arena mentioned that they are currently undergoing two pediatric / infant (under age 2) studies. One has recruited 1100 patients and the other 500 patients, to achieve a change to label and indication. Karen was uncomfortable with Utah Medicaid DUR Board overruling what the FDA Pediatric Advisory Board ruled. DUR Board agreed that there will be no changes to current prior authorization requirements for children younger than 2 years. Proposal to change the age limit on either Elidel or Protopic did not pass the committee. Dr Bushnell requested the DOH bring something to the Board about what the criteria is for the prior authorization.

7. Apidra was not discussed due to time expiring. Discussion will be moved to a future meeting.

Next meeting set for August 10, 2006

Meeting adjourned.

The DUR Board Prior approval sub-committee convened and considered 5 petitions. Drug Histories were for 12 months unless otherwise noted.

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Petitions to the DUR Board
July 13, 2006

Patient #1
Keith Tolman, MD with the University of Utah Gastroenterology Clinic is requesting consideration by the Board for Zelnorm for a 48 year old female client diagnosed with nausea and vomiting with "other problems" including IBS constipation dominant. On 4/4 the results of a dual phase solid and liquid gastric emptying scan found the results consistent with delayed mild to moderate delayed gastric emptying. Nausea and vomiting occur occasionally according to 3/28/06 progress notes provided with the request. On this date, the notes also list "(?) gastroparesis, 536.3, inadequately controlled" with other diagnoses. **The Board Approved this petition.**

Patient #2
Dr Louis Morales, MD with Plastic Surgery Associates is requesting prophylactic pre-surgical administration of Procrit for a 6.5 month old male diagnosed with soft palatal cleft, hypospadias, and metopic craniosynostosis. Surgery will be for craniosynosotosis repair. **The Board denied this petition.**

Patient #3
Mark Boyer, FNP with the Dixie Regional Medical Center, is requesting Provigil 200mg twice daily for a 34 year old female with excessive daytime sleepiness. Baseline polysomnography was performed on 12/8, 2005 which demonstrated n Apnea-Hypopnea index overall of 5.6 per hour and 25.6 per hour during REM sleep. On 2/2/06 a CPAP titration study found that the apnea events were eliminated with a pressure of 8 to 14 cm/H20. The patient was placed on CPAP therapy at this setting. After trying CPAP for approximately 2 months, there was no improvement in the patient's sleep or daytime sleepiness, and CPAP therapy was discontinued. Symptoms continued with severe daytime sleepiness and difficulty functioning. As a result of this, the patient was provided with samples of the medication Provigil, initially starting at a dosage of 200mg in the AM. At this dose the patient noticed increased alertness and mental status, but found that around 3-4 pm her energy waned. The dosage was increased to twice daily which eliminated the afternoon drop in energy. **The Board denied this petition.**

Patient #4
This petition is re-submitted from the June meeting. The Board requested clarifying information:

[The fourth petition to the Board comes from Kristine Hindert, MD from the Children's Center requesting Focalin 5mg twice daily for a 4 year 10 month old **[date of birth 7/4/01- child is now 5 years old]** male who has been "very aggressive leading to expulsions from 5 daycare centers. He has ADHD and a mood disorder. He has been in a therapeutic preschool since 9/24/04. Despite intensive day treatment services in this program, his latest daycare threatened to expel him." Dr Hindert has tried him on Trazodone which help his aggression but not his disruptive behavior, and Adderall XR which helped his disruptive behavior but caused severe moodiness. Aggression worsened and since Adderall could not be increased due to side effects, Risperdal was added with questionable response.

Dr Hindert then explains that Concerta was tried with excellent response but poor sleep. She then tried regular Methylphenidate but he did poorly due to "rapid metabolizing." Wellbutrin was also ineffective. He is now being tried on Strattera. Dr Hindert states that she recently has tried him on Focalin, and he has done extremely well with no side effects].

Additional information requested included progress notes that support trials of other therapies not showing in the medication history, results from the Strattera trial, and information regarding use of a mood stabilizer. Dr. Hindert writes that bupropion made him less angry, but he was still inattentive for academic tasks, and thus the Strattera trial was undertaken. She reports that he had increased rages, and had little benefit on the Strattera. Trials of Focalin have been the only treatment that has provided optimal results. **The Board approved this petition.**

Patient #5

John Fang from the University of Utah Gastroenterology Division, is requesting Zofran 4mg q 8h prn nausea for 31 year old male with a complicated medical history stemming from esophageal atresia as an infant. He underwent esophagectomy in 2005. He was last seen on May, 2006 with complaints of abdominal cramping/diarrhea after being treated for C. Diff. He has been hospitalized over the winter with several bouts of pneumonia. He recently had a colonoscopy and most recent June 27 visit was for F/U of colonscopy. Most cramping and nausea follows meals; he has been using Promethazine and metoclopramide without significant response. He has not had any episodes of vomiting. Zofran from ER visits has worked best for his nausea. He had upper endoscopy dilation in Mid-May for complaints of dysphagia, which has improved since. He has occasional heartburn. **The Board approved a 90 day trial for #60. The patients medication history is to be provided to the physician for his review pending further treatment.**